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Instruction in the Responsible Conduct of Research: An Inventory of Programs and Materials within CTSAs

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Abstract

The National Institutes of Health (NIH) require instruction in the responsible conduct of research (RCR) as a component of any Clinical and Translational Science Award (CTSA). The Educational Materials Group of the NIH CTSA Consortium's Clinical Research Ethics Key Function Committee (CRE-KFC) conducted a survey of the 38 institutions that held CTSA funding as of January 2009 to determine how they satisfy RCR training requirements. An 8-item questionnaire was sent by email to directors of the Clinical Research Ethics, the Educational and Career Development, and the Regulatory Knowledge cores. We received 78 completed surveys from 38 CTSAs (100%). We found that there is no unified approach to RCR training across CTSAs, many programs lack a coherent plan for RCR instruction, and most CTSAs have not develop unique instructional materials tailored to the needs of clinical and translational scientists. We recommend collaboration among CTSAs and across CTSA key function committees to address these weaknesses. We also requested that institutions send electronic copies of original RCR training materials to share among CTSAs via the CTSpedia website. Twenty institutions submitted at least 1 educational product. The CTSpedia now contains more than 90 RCR resources.

Keywords

Responsible conduct of research; research integrity; research training

Introduction

Since 1990, the National Institutes of Health (NIH) have required instruction in the responsible conduct of research (RCR) for all trainees supported by National Research Service Awards.1 Consistent with this, the current request for applications (RFA) for the NIH Clinical and Translational Science Award (CTSA) requires research education,

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training, and career development programs to "include a description of programs designed to provide formal and informal instruction in scientific integrity or the responsible conduct of research" (RFA-RM-09-004). In 2000, the Office of Research Integrity (ORI) identified 9 core areas for RCR instruction: (1) data acquisition, management, sharing, and ownership; (2) mentor/trainee responsibilities; (3) publication practices and responsible authorship; (4) peer review; (5) collaborative science; (6) human subjects; (7) research involving animals; (8) research misconduct; and (9) conflict of interest and commitment.2 While ORI's policy specifying core areas for instruction was suspended in 2001, many instructional programs have adopted its framework for establishing curricular content.3 Nevertheless, training programs vary widely in their scope, content, formats, and instructional methodologies.1, 4

The study reported in this article was conducted by members of the Educational Materials Group of the NIH CTSA Consortium's Clinical Research Ethics Key Function Committee. Our purpose was twofold. First, we aimed to identify how CTSA programs currently satisfy NIH's RCR instructional requirements for trainees. In particular, we wanted to determine: whether instruction is offered to individuals other than trainees; what are the most commonly used instructional materials and programs; and whether any RCR materials were specially developed for use within CTSA programs. Second, we sought to identify and to collect RCR training materials and curricular resources developed by CTSA programs and to host them on the CTSpedia website (www.ctspedia.org) for wide dissemination and use.

Methods

Using publicly available information, we contacted by email the directors of the "Clinical Research Ethics," "Education and Career Development," and "Regulatory Knowledge" cores at the 38 institutions that held CTSA funding as of January 2009. An 8-item questionnaire on RCR instruction was embedded in an email; respondents completed the questionnaire in a reply email. In cases where one or more core directors indicated that RCR education is handled by another individual at the institution, the contact information for that individual was obtained and the survey was forwarded to the RCR education coordinator as well. Specific items are described below in the results section.

We focused on establishing and analyzing reliable institutional data. This involved key decisions to be made when more than one individual from an institution responded. If the individuals' responses simply repeated information, we entered just one response. When individual respondents identified different training programs within a single CTSA that trainees needed to complete (e.g., an institution-wide required online course and an onsite course just for CTSA trainees), we entered all data. In the few cases in which individual respondents contradicted each other, we used the responses that were more specific (e.g., if one individual said the CTSA required no training and another individual provided specific information on a training program, we used the response that provided specific information).

If respondents indicated that their program had developed any original RCR training materials, they were asked to provide an electronic copy of the materials and to grant permission to post them on the CTSpedia website. Respondents were also asked to provide information regarding what, if any, textbooks or online content were used in their courses.

The Institutional Review Board at the University of California, Davis, approved the project as exempt and permission was obtained from authors and creators for the collection and posting of all materials. Questionnaires were sent out in January 2009.

Results

Questionnaire Results

Seventy-eight (78) completed surveys were received from 38 CTSAs (100% of CTSAs funded as of January 2009).

All but one institution reported offering some form of RCR instruction within their CTSA framework. Thirty-four (34) institutions provided contact information for a separate RCR education director or coordinator. Table 1 presents a basic description of the RCR training programs within CTSA institutions.

Respondents reported a wide variety of curricular materials in use for RCR instruction across the CTSA programs. Nineteen (50%) of the CTSA programs reported using an online training program. Ten CTSA programs rely on the online RCR curriculum offered by the Collaborative Institutional Training Initiative (CITI) program, and six use other online programs.

To gain some further understanding of the RCR curricular content covered in training programs, our questionnaire inquired whether institutions use a textbook in their RCR training programs. Eleven institutions left the item blank, 13 responded that they do not use a textbook, and 14 identified one or more textbooks in use in their program. Table 2 identifies those textbooks that are used by at least 2 institutions. Three institutions identified other textbooks. Several institutions noted in the comments section that they use only selections from the textbooks identified.

Inventory of Materials

Table 3 below presents the number and percentage of CTSA programs that have developed original RCR training materials of some type. If a program had developed original materials, we asked if they would be willing to send a copy to post on the CTSpedia website. Twenty (20) institutions submitted at least one educational product. The publicly accessible CTSpedia website now contains more than 90 RCR resources, including links to websites, case studies, PowerPoint slides, readings in pdf format, and videos. These materials are indexed in three ways: By institution, by topic, and by type or format. Materials are hosted online at: http://www.ctspedia.org/do/view/ResearchEthics/WebHome.

Discussion

This survey and inventory project adopted a simple design that enabled 100% participation from the CTSA programs, provided basic descriptive data on CTSA programs' RCR instruction programs, and collected over 90 educational materials that can be shared across institutions. In general, we found wide variability regarding the method of RCR instruction, materials used in such courses, and who is required to complete RCR training.

Several conclusions may be drawn from our survey results. First, there is no unified approach to RCR training across CTSAs. There is significant variation in scope, content, and approaches to RCR instruction. While this is not necessarily a problem, this finding does raise questions regarding the ideal RCR curriculum and whether RCR instructional resources are adequate across institutions.

Second, many CTSA programs lack a coherent plan for RCR instruction. Directors of different cores often had independent plans for RCR instruction or different impressions of how RCR instruction is delivered within the same institution. While contacting three key function directors helped to contribute to 100% participation from CTSA institutions, it also

meant that we frequently received more than one set of responses from an institution. In such cases institutional responses sometimes contradicted each other. For example, 6 questionnaires stated that their CTSA and their institution offered no RCR training; however, in 5 of those 6 instances, another returned questionnaire from the same institution identified specific programs and a contact person. The widespread lack of a coherent plan for RCR training may be partially due to the fact that the initial two CTSA program announcements from NIH required applications to address clinical research ethics consultation and ethics research programs, but did not remind institutions of the NIH requirement that trainees receive instruction in RCR (which is broader in scope than clinical research ethics). It is likely that plans for RCR instruction will improve as new CTSAs respond to updated RFAs and existing programs prepare to submit grant renewal applications.

Third, CTSAs overall have not developed unique instructional materials tailored to clinical and translational science, such as how to handle first-in-human trials or collaborations between bench and clinical researchers. This finding runs counter to a recommendation from the Council of Graduate Schools and several RCR experts that RCR instruction should be tailored to the specific need and experiences of trainees.3, 12-16

There are several limitations to this work. First, a more sophisticated design (e.g., a content analysis of all course syllabi with interviews with instructors) would have provided more information, but at significantly higher cost and most likely with inferior participation rates. 4, 17-19 Second, we did not address the significant issue of whether existing RCR training programs are effective in achieving their intended purposes. This limitation is, unfortunately, currently true of most studies of RCR programs.15, 20-22 While important, this aim was beyond the scope of our current project.

Conclusions

Reflecting upon responses received to our survey, we offer the following recommendations for RCR instruction within CTSA programs.

First, CTSA programs, both individually and collectively, should develop a coherent plan for RCR instruction. This process should involve a coordinated effort by PIs with representatives from the Clinical Research Ethics, Education and Career Development, and Regulatory Knowledge cores.

Second, clinical research ethics instructors may be well positioned to develop and deliver RCR programs that are tailored to clinical and translational scientists. A recent Delphi study suggested that such training should focus not only on conveying relevant knowledge but also on fostering ethical problem solving skills.16 Moreover, it should address the unique challenges that arise in clinical and translational research.

Third, we recommend that CTSA programs inform faculty and staff at their institutions of the wide array of resources available on the CTSpedia, which provides valuable resources for researchers as well as RCR instructors. The materials posted on the CTSpedia should raise awareness of new approaches to RCR and increase the use of original and high-quality materials developed by CTSA programs.

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Roadmap for Medical Research. Its contents are solely the responsibility of the authors and do not necessarily represent the official view of NCRR or NIH.

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Table 1

Survey Responses Describing Training Programs

	n	%
Do you offer RCR training within your CTSA?	37 yes	97%
Do you offer online training? *	19 yes	50%
Do you offer onsite, in person training? **	34 yes	89.5%
Who is required to take the CTSA RCR course?		
Trainees (formerly under the T32, K12 or K30 programs)	31	81.6%
All key personnel	12	31.6%
All research personnel	9	23.7%
All residents	10	26.3%
All post-docs	21	55.3%
Other	18	47.4%
Did not respond to question	4	10.5%

*Most CTSAs that use an online training program supplement it with some onsite training, e.g., a lecture series. Therefore the total % of online and onsite training programs exceeds 100%.

Table 2

Textbooks for RCR Instruction used within CTSA Programs

Book Title	**n**	**%**
ORI Introduction to the Responsible Conduct of Research 5	6	16%
Scientific Integrity: Text and Cases in Responsible Conduct of Research 6	6	16%
Making the Right Moves: A Practical Guide to Scientific Management for Postdocs and New Faculty, 2 Ed 7	4	11%
On Being a Scientist 8	4	11%
Responsible Conduct of Research (Shamoo & Resnick) 9	4	11%
The Ethical Dimensions of the Biological and Health Sciences 10	2	5%
The Responsible Conduct of Research (Beach) 11	2	5%

Table 3

Original Training Materials

Have you developed any original RCR training materials that you use within your CTSA?	**N**	**%**
Syllabus and/or reading list	20	53%
Slides / Power Point presentations	20	53%
Cases for discussion	19	50%
Video	5	13%
Other	9	24%
We have no original materials	7	18%
Did not respond to question	8	21%